UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff,	)	
vs.	)	1:02-CV-1844-SEB - VSS
BARR LABORATORIES, INC., Defendant.	)	

ORDER SUSTAINING IN PART AND OVERRULING IN PART OBJECTIONS BY LILLY TO MAGISTRATE JUDGE'S ENTRY ON BARR'S MOTION TO COMPEL

Plaintiff Eli Lilly and Company ("Lilly") has interposed two objections to the Magistrate Judge's order granting Defendant Barr Laboratories, Inc's ("Barr") Motion to Compel certain discovery disclosures which had been sought by Barr and resisted by Lilly in this patent dispute. As explained below, we overrule Lilly's objection to being required to produce marketing documents relating to the effect of Evista on reducing the risk of breast cancer, but we sustain Lilly's objection to disclosures of sampling lots of Raloxifene that were manufactured before 2002.

1. Re: Disclosure by Lilly of Marketing Materials Relating to Evista's Secondary Effect in Reducing the Risk of Breast Cancer: Lilly has patented a substance which it produced and marketed under the name Evista to treat post-menopausal osteoporosis. Apparently, the drug has been determined to have the highly desirable secondary property of reducing the risk of breast cancer.

Lilly sued Barr for infringement of this patent, and Barr rejoined with claims of

patent invalidity asserted in part on the grounds of obviousness. In overcoming Barr's defense of obviousness, Lilly has indicated that it intends to prove the commercial success of Evista in treating post-menopausal osteoporosis. Barr theorizes that Lilly's commercial success in developing and marketing Evista was due to some degree to the "unclaimed advantage" of the drug in reducing the risk of breast cancer, not only in treating osteoporosis. For this reason, Barr has sought to have Lilly disclose in discovery any marketing materials that Lilly generated which referenced or were otherwise directed toward this alleged "unclaimed advantage" of the patented invention in order to permit Barr to determine the influence of such marketing on the commercial success of the patented product. Lilly has resisted these requests for disclosure on the grounds that at trial Barr will be foreclosed as a matter of law from seeking to defeat Lilly's proof of the commercial success of Evista on the grounds that its success was driven in whole or in part by the secondarily beneficial property of the drug in reducing the risk of breast cancer.

The Magistrate Judge, after conducting a lengthy hearing at which the issues were fully developed prior to a decision, ruled in favor of Barr and required Lilly to provide the requested discovery by searching for and gathering together and producing any of its marketing documents that may contain information referencing the reduced risk of breast cancer associated with or referencing the use of raloxifene to treat osteoporosis. We do not find the decision by the Magistrate Judge to be either clearly erroneous or contrary to law. In fact, we concur in the Magistrate Judge's reasoning that "if Barr can show that

Evista would not have enjoyed commercial success but for its possible breast cancer prevention benefit," that would clearly be relevant to the obviousness issue analysis.[1]

Stated otherwise, despite Lilly's assurances that it does not intend to prove that Evista is commercially successful as a result of its property of reducing the risk of breast cancer and that ninety-eight percent of Evista prescriptions are for post-menopausal osteoporosis, which prescriptions and sales form the basis of Lilly's commercial success argument (Lilly's Reply (Dkt # 170), page 1), it is possible nonetheless that some portion of those prescriptions might have been issued for the dual purpose of treating osteoporosis and breast cancer prevention, even though they only referenced on their face treatment of osteoporosis. Because the drug was known to accomplish the additional treatment goal of reducing breast cancer, the commercial success data arguable would reflect both treatment benefits. Lilly's marketing materials may or may not ultimately substantiate Barr's claim; at this juncture, Barr is entitled to investigate in an effort to determine whether Lilly's marketing efforts might have generated or otherwise influenced

[1] We would be hard-pressed to improve on the clarity of Magistrate Judge Shields' analysis as set out in her Entry, at page 5: "However, the commercial success of Evista, as with any product, depends upon it being chosen over the alternative products available in the marketplace. If physicians are choosing to prescribe Evista instead of other available drugs approved for the treatment and prevention of osteoporosis because they believe that Evista may decrease their patients' risk of cancer and no other commercial osteoporosis drug has shown this benefit, then perhaps Evista's commercial success is not due to the 'unique characteristics of the claimed invention(s)," but rather to an unpatented aspect of Evista. In other words, if Barr can show that Evista would not have enjoyed commercial success but for its possible breast cancer prevention benefit, it seems to the magistrate judge that this would be relevant to the obviousness analysis." In contrast to Lilly's view, we are not convinced at this juncture that this rationale warranting discovery disclosures will lead to inadmissible evidence or is contrary to law.

Lilly's commercial success with the drug.

The Magistrate Judge's Order (Dkt # 147) is therefore AFFIRMED with regard to requiring Lilly to disclose its marketing materials referencing Evista's property of reducing the risk of breast cancer.

2. Re: The Requirement that Lilly Produce Sample Lots of Raloxifene Manuafactured Before 2002: Barr sought this discovery in order to confirm that the commercialized form of Evista was, in fact, the patented invention and to confirm the point in time at which Lilly conceived of and began production of the '811 particle size patent. Barr's request covers the past twenty years of Lilly's development of this product. Lilly seeks to have the period of production of Evista sample lots limited to three years, consistent with related FDA requirements for the retention of sample product, noting in addition that Lilly did not launch Evista until December 1997, shortly after the FDA approved it for commercial sale, and that Lilly would only be relying upon the post-launch sales in this litigation to demonstrate Evista's commercial success.

Because Lilly has already voluntarily produced twenty samples from raloxifene lots that were manufactured within the past three years and because it has represented in its filings with the court in conjunction with this discovery dispute that the manufacturing and release specifications for Evista have not changed since its introduction in 1997, we will not require further production by Lilly, unless Barr's testing of the samples already provided by Lilly puts the lie to Lilly's representations by producing results that suggest

that earlier samples would likely be substantially different from those already produced. In addition, we note that Lilly has stated that it has fully disclosed to Barr the earliest dates of conception and reduction to practice which Lilly intends to assert in this case, which thus moots the necessity of further sample production by Lilly.

This portion of the Magistrate Judge's Order (Dkt # 147) is OVERRULED IN PART, in light of Lilly's partial compliance which disclosures the Court deems sufficient; the remaining discovery requirements relating to the production of samples are overruled and denied as moot. IT IS SO ORDERED.

Date: 06/13/2005

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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